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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,681	11/08/2001	David G. Barkalow	112703-198	.4991

29156 7590 10/24/2006

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EXAMINER

SHEIKH, HUMERA N

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,681

Applicant(s)

BARKALOW ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 41-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
7-16-06

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/14/06; 2/14/02; 2/15/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election Requirement, Applicant's Arguments/Remarks and the Information Disclosure Statement (IDS), all filed 08/14/06 is acknowledged.

Applicant's election with traverse of Group II (Claims 25-40) in the reply filed on 08/14/06 is acknowledged. The traversal is on the ground(s) that "There is no basis for finding a lack of restriction to be a serious burden on the Examiner when the examination of the instant claims by the Examiner has continued to this point in the prosecution without a restriction requirement. The Patent Office has examined the claims of this application numerous times, and, only now, has determined that these criteria (independent/distinct inventions & serious burden on Examiner) are met. The restriction requirement is improper". This is not found persuasive because, as pointed out in the restriction requirement filed 07/14/06, the inventions, as now presented, are capable of supporting a separate patent within the art, as evidenced by their different classifications, different searches in both patent and non-patent databases, as well as different enablement and patentability issues and there is no expectation that the searches would be coextensive. This ultimately creates a serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-19 and 41-46 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

Art Unit: 1615

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/14/06.

Claims 16-19 and 25-46 are pending in this action. Claims 16-19 and 41-46 have been withdrawn. Claims 1-15 and 20-24 have previously been cancelled. Claims 25-40 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (U.S. Pat. No. 5,433,960).

The instant invention is drawn to a composition consisting essentially of a stand alone pullulan-free edible film, said film comprising: an effective amount of at least two film forming agents comprising cellulose and starch; an effective amount of at least one bulk filling agent; and an effective amount of at least one plasticizing agent, the agents forming a stand alone edible film having film properties substantially similar to a pullulan-based edible film, wherein the composition dissolves quickly in the mouth of a user.

Meyers ('960) teaches an edible film composition and method for making thereof comprising *edible film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, modified starches, dextrin, maltodextrins, gelatin, protein, zein, polyols and combinations thereof including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more *active agents* located in the edible film, which include *dental agents* (i.e., plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors, phosphates, sodium

Art Unit: 1615

bicarbonate, remineralizing agents); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15- col. 4, line 18); (col. 6, lines 20-44); (col. 7, line 64 – col. 8, line 29); (col. 9, lines 13-34); (col. 10, lines 15-17); (col. 11, lines 49-55) and claims.

Meyers teaches that suitable water-soluble film forming agents include, besides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methylcellulose, hydroxypropylcellulose and sodium hydroxymethylcellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The percent ranges of film-forming agents taught by Meyers are overlapping ranges with the instant claims (instant range is ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc, dicalcium phosphate and the like are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (col. 8, line 7 thru col. 10, line 30) (instant range is <20%).

With regard to the instantly claimed 'method of treating halitosis' (claim 19), it is the Examiner's position that since Meyers explicitly teaches active agents comprised of oral dental care agents, such as pH buffers, plaque inhibitors, antimicrobial agents, phosphates, etc., then one of ordinary skill in the art desiring to improve conditions of bad breath or halitosis, would turn to the teachings of Meyers, based on the dental care agents taught therein. The dental agents

(i.e., plaque inhibitors, antimicrobials) taught by Meyers would be equivalent and applicable towards the treatment of bad breath or halitosis (see col. 11, lines 49-57).

The film composition of Meyers provides for effective film-forming polymers, bulk fillers, flavoring agents, plasticizers, oral/dental care agents, softeners, emulsifiers and the like.

It is the position of the Examiner that given the teachings of Meyers, it would be *prima facie* obvious for one of ordinary skill in the art to use the specifically disclosed combination ingredients of Meyers to provide for a film composition that enables delivery of active ingredients, allows for flexibility of the film, as well as breath freshening, germ killing properties, flavor enhancement, etc. The expected result would be an edible film composition that offers maximal and optimal benefits to the consumer.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) as applied to claims 25-39 above and further in view of Zerbe *et al.* (U.S. Pat. No. 5,948,430).

Meyers, as discussed above, teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, modified starches, dextrans, maltodextrans, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches various acids that include for example, stearic, lauric, palmitic, arachidic, oleic, linoleic and eladic acids at column 8, lines 5-11. Meyers does not teach an acid from the

Art Unit: 1615

instant selective group of claim 40 (citric, lactic, malic, ascorbic, succinic, adipic, fumaric, tartaric acid).

Zerbe et al. ('430) teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids taught include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the particular acids (*i.e.*, tartaric, citric) of the film composition taught by *Zerbe et al.* within the edible film composition of Meyers. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because *Zerbe et al.* teach a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (*i.e.*, tartaric, citric) which function to provide an enhancement of flavor to the composition. The expected result would be an edible film-forming composition that imparts enhancement of flavor, taste and freshness in the mouth of the consumer.

Response to Arguments

Applicant's arguments filed 08/14/06 have been fully considered but they are not persuasive.

Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 16-19, 25-39 and 41-46 over Meyers (US 5,433,960) and the 35 U.S.C. §103(a) rejection of claim 40 over Meyers (US 5,433,960) in view of *Zerbe et al.* (US 5,948,430) stating, "Meyers does not teach or suggest a composition consisting essentially of a stand-alone pullulan-free edible film composition as in

Art Unit: 1615

the claimed invention. Meyers requires structural support, i.e., gum for its film coating. Applicants have surprisingly found and clearly indicated the basic and novel characteristics of the claimed invention in the specification at, for example, page 8, lines 26-29, to be a stand along film that is self-supported requiring no support structure. A support structure as is taught by Meyers would materially affect the basic and novel characteristics and properties of the claimed invention. For example, the composition taught in Meyers does not quickly dissolve in the oral cavity of an individual as in the claimed invention. Therefore, Meyers does not teach or suggest a composition consisting essentially of a stand-alone pullulan-free edible film. Claim 40 stands rejected as being unpatentable over Meyers in view of U.S. Patent No. 5,948,430 to Zerbe et al. (Zerbe). Applicants respectfully submit that Zerbe fails to cure the deficiencies of Meyers mentioned above, and, therefore, the rejection should be withdrawn.”

Applicant’s arguments have been carefully considered but were not found persuasive. Applicant’s arguments of a “stand alone” edible film is not persuasive since the limitation of a ‘stand alone’ film is not a change in form that imparts a *patentable* distinction over the films of the art of record. The ‘stand alone’ film as instantly claimed reads on the chewing gum taught by Meyers. Meyers teaches an edible film composition comprising edible film-forming agents, bulk filler agents, plasticizers, active agents that include dental agents, flavor enhancers, sweeteners, softeners and the like. Thus, Meyers teaches the incorporation of the same ingredients, formulated for use in the same field of endeavor and used for the same purpose as that claimed by Applicant. The prior art’s film also provides for the same objectives as desired by Applicants, such as increased moisture stability, release of active ingredient, flexibility (from plasticizers/softeners), flavor enhancing and germ-killing (due to antimicrobials) and thus

Art Unit: 1615

sufficiently provides for all properties instantly desired. Zerbe *et al.* was relied upon for the teaching of specific acids (tartaric & citric acid) in their film and thus clearly resolve the deficiency of Meyers. It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results, which accrue from a composition that consists essentially of a "stand alone" film composition. The prior art clearly recognizes and teaches an edible film comprised of the same components for use in the same field of endeavor as the Applicant. Thus, given the explicit teachings of the art, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1615

system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

October 17, 2006

Humera N. Sheikh
TC-1600

hns